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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,059	07/22/2003	Richard G. Wilde	10589-015-999	8259
20583	7590	06/06/2006	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			OLSON, ERIC	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 06/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/625,059	WILDE ET AL.	
	Examiner	Art Unit	
	Eric S. Olson	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.138(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 20-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>Nov. 26, 2003</u> . | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

This office action is in response to Applicant's election filed May 15, 2006 wherein group I is elected and specific compound and disease species are elected. Claims 1-19 are pending in this application and examined on the merits herein.

Applicant's election of group I drawn to a method of treating or preventing a disease resulting from a somatic mutation comprising administering to a patient in need thereof an effective amount of a compound having structure (I) as defined in the claims, is acknowledged. Because applicant did not distinctly and specifically point out any errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Applicant's election without traverse of the compound species 6-amino-5-nitro-4-(β -D-ribofuranosylamino)pyrimidine, commonly known as clitocine, and the disease species cancer, is acknowledged. Therefore, claims 1-19 in part have been examined insofar as they read on the elected invention.

Groups II-XII are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected groups, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on May 15, 2006.

Claim Rejections – 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of specific p53-associated tumors such as the CAO-V-3 cell line demonstrated in the specification by the administration of the elected compound, does not reasonably provide enablement for treatment of every type of cancer in existence. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: The claimed invention is a method for treating cancer by the administration of a nucleoside analogue which is capable of restoring function to genes disrupted by nonsense mutations. It is claimed that the compound restores function of tumor suppressor genes such as p53, thus inhibiting the growth of the cancer.

The state of the prior art: The skilled artisan would view cancer as a group of maladies not treatable with one medicament or therapeutic regimen. No single

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chemotherapeutic drug is useful for the treatment of every case of cancer. Indeed, some types of cancer do not respond well to any known chemotherapeutic drugs. According to the Merck Manual of Diagnosis and Therapy (Reference included with PTO-892), Hepatocellular carcinomas and renal cell carcinomas are not generally improved by chemotherapy. Acute lymphoblastic leukemia, on the other hand, responds well to a number of drugs, including vincristine, anthracyclines, and asparaginases, while acute myelogenous leukemia, on the other hand, responds to fewer drugs and is usually treated with cytarabine in combination with daunorubicin or idarubicin. Breast cancer, on the other hand, is best treated with surgery and/or radiation, but the prognosis can be improved by the addition of adjuvant chemotherapy.

The relative skill of those in the art: The level of skill in the art is high.

The predictability or unpredictability of the art: As mentioned above, no single treatment is effective for all cancers. Different cancers vary widely in their response to different chemotherapy regimens. According to the Oxford Textbook of Oncology, (Reference cited in PTO-892) "The important criteria for the tumor include its sensitivity to cytostatic drugs, its clinical stage and its mass, the presence of measurable lesions or biochemical markers, and, finally, growth characteristics," as well as, "*In vitro* sensitivity tests have been disappointing. They predict well for resistance but are of little use for sensitivity," (p. 451, right column, second paragraph) and, "For many types of cancer the potential benefit of chemotherapy has not been demonstrated in well-designed clinical trials."

Based on the known teachings of the prior art such as that stated above, one skilled in the art would recognize that it is highly unpredictable in regard to the treatment in the instant case, including treating numerous and various tumors, for example: gynecological tumors, ovarian carcinomas, testicle tumors, prostate carcinomas, skin cancer, kidney cancer, bladder tumors, esophagus carcinomas, stomach cancer, rectal carcinomas, pancreas carcinomas, thyroid cancer, adrenal tumors, various types of leukemia and lymphomas, Hodgkin's disease, tumor illnesses of the CAN, soft-tissue sarcomas, bone sarcomas, benign and malignant mesotheliomas, especially intestine cancer, liver cancer, breast cancer, bronchial and lung carcinomas, melanomas, acute and chronic leukemias and benign papillomatosis tumors, by performing the necessary experimentation to develop an optimized protocol for treating said cancers. Further varieties of cancer which must also be treated successfully by the claimed invention are recited in instant claim 14.

Furthermore, the mechanism disclosed by the specification is not applicable to all cancers. The compounds of the claimed invention are disclosed to act by restoring full-length translation of genes disrupted by nonsense mutations. (P. 37, lines 16-20) However, the mutations which lead to cancer may be of other types, such as missense, gain-of-function, or frameshift mutations, which are not necessarily restored by this mechanism. P. 2, lines 27-28 of the instant specification disclose that only 7% of reported p53 mutations are nonsense mutations. Therefore the other 93% are not expected to be susceptible to the claimed therapeutic method. Additionally, Zambetti et al. (Reference included with PTO-1449) discloses that a mutant p53 gene may cause

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cancer through a gain-of-function mutation as well as a loss-of-function mutation. (p. 857, right column, second paragraph) Overcoming oncogenesis caused by this mechanism would require that the mutant p53 be suppressed, inhibited, or otherwise counteracted. Merely restoring a low level of wild-type p53 expression would have no effect on the course of the disease.

The Breadth of the claims: Instant claims 1-13 are drawn to methods for treatment of any cancer with the elected compound. Instant claims 14-18 are drawn to methods for the treatment of a broad variety of recited cancers. Instant claim 19 is drawn to methods of inhibiting the growth of cancer cells *in vivo*.

The amount of direction or guidance presented: The probable mechanism by which the claimed therapeutic method exerts its effects is disclosed. Protocols are provided for *in vitro* and *in vivo* inhibition of cancer cells. Clinically relevant properties such as the toxicity or therapeutic index, are not disclosed.

The presence or absence of working examples: The only *in vivo* working example provided in the specification is drawn to a treatment of a specific tumor cell line, CAOV-3, bearing a p53 nonsense mutation. *In vitro* examples are given for several p53 nonsense mutant cell lines: CAOV-3, NCI-H520, CALU-6, HCC1569, NCI-H774, and HCl-H1926. No working examples are given for tumor cell lines bearing mutations in genes other than p53, or for cell lines in which the oncogenic mutation is a missense or frameshift mutation. No examples are given for the treatment of cancers resulting from mutations in genes other than p53.

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable art such as cancer chemotherapy. See MPEP 2164.

The quantity of experimentation necessary: In order to practice the invention for all cancers beyond those disclosed in the specification, one skilled in the art would develop specific therapeutic regimens for each general type of cancer bearing a nonsense p53 mutation. One skilled in the art would have to perform further experimentation to develop therapeutic methods for treating cancers not associated with a single nonsense mutation, as these cancers are unlikely to be treatable through the mechanism disclosed in the instant specification. This would involve a process of optimizing and testing various regimens *in vivo* for each type of cancer being treated. This process would involve unpredictable experimentation which would constitute an undue experimental burden on the practitioner, with no guarantee that success is even possible for each case.

Genentech, 108 F.3d at 1366, states that, “a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion.” And “patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable.”

Therefore, in view of the Wands factors, as discussed above, especially the unpredictability of the art and the breadth of the claims, Applicants fail to provide information sufficient to practice the claimed invention for the treatment of all types of cancer.

Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating certain forms of cancer by administering the elected compound, does not reasonably provide enablement for prevention of cancer by administering the elected compound. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

The Nature of the invention: The claimed invention is a therapeutic method for the prevention and treatment of cancer, involving the administration of a specific compound to a patient in need thereof. Because every living mammal is at risk of developing cancer, the patient population is not limited to those actually suffering from cancer. The invention is supposed to work by restoring full-length expression of tumor suppressor genes, particularly p53, which have been disrupted by nonsense mutations.

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The state of the prior art: The state of the art for the treatment of nonsense mutations does not include any therapies directed to preventing nonsense mutation from occurring or preventing the occurrence of disease in those carrying them. Although various factors, such as exposure to radiation or certain chemicals, are known to increase or decrease a subject's risk of developing cancer, no methods for completely preventing the development of cancer by administration of a compound have been reported. Thus there is no precedent in the prior art for the prevention of this class of diseases, as opposed to treatment.

Aminoglycosides, the main class of nonsense suppressor agents known in the prior art, are known to be toxic as a result of their ability to disrupt normal protein synthesis and cause the misincorporation of amino acids into synthesized proteins. Long-term systemic administration of aminoglycosides is therefore not advisable. Because the elected compound is disclosed to possess a biological activity similar to that of aminoglycosides, it is expected to possess similar toxicity, and is in fact known in the art as an insecticide.

The relative skill of those in the art: The relative skill of those in the art is high, with a typical practitioner having obtained a PhD or equivalent advanced degree.

The predictability or unpredictability of the art: Prevention of a disease is not the same as treatment of said disease. In order to prevent a disease, as opposed to merely delaying or reducing its symptoms, a treatment must either render the subject completely resistant to said disease after a single treatment or a limited number of treatments, or else, when continued indefinitely, continue to completely suppress the

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occurrence of said disease. In order to practice a preventative method, one of skill in the art must know the answer to several questions in addition to the effectiveness of the therapy in short-term relief of symptoms, including:

1) What is the duration of a single course of therapy? How often must the therapy be administered to completely suppress the disease?

2) Does the subject develop tolerance to the therapy over time? Does the disease eventually progress to a point where the therapy is unable to completely suppress all symptoms?

3) What are the long-term effects of the therapy? Does it cause progressive damage to the kidneys, liver, or other organs? Does the active agent accumulate in the subject's tissues? Is the minimum dose necessary to completely prevent the disease safe for long-term administration? Are there any steps that can be taken to reduce side effects?

For this reason, many therapies which are suitable for short-term relief of symptoms are not suitable for lifelong prevention of disease. For example, antibiotics, chemotherapeutics, and antiviral drugs are not normally administered to healthy subjects in order to prevent the development of infection or cancer. This is especially the case when the drug in question, like most or all cancer drugs, possesses significant side effects which would be burdensome or life-threatening if therapy is continued indefinitely, and which outweigh the potential benefits of the therapy if the drug is administered to a healthy subject.

The Breadth of the claims: Claims 1-18 are drawn to a method of treating or preventing cancer. No limits are provided as to the scope of prevention claimed. Thus, to be fully enabling, the specification must disclose a therapeutic method capable of preventing anyone from ever being afflicted with cancer.

The amount of direction or guidance presented: All of the references to the potential of Clitocine as a cancer therapeutic disclosed or cited by the Applicant were published within the last twenty years, and none describe any experiments continued for a sufficient period of time to determine the long-term effectiveness of the disclosed therapy for preventing cancer over a subject's entire lifetime, rather than delaying the onset or reducing the symptoms of the disease. As the average human lifespan is between seventy and eighty years, the Applicant, or any other physician or researcher, could not have observed the long-term efficacy, or lack thereof, of the claimed therapeutic method. Rather than claiming an actual invention, the term "prevention" merely denotes a hope or prediction. The specification fails to address this concern or give any rationale as to why the disclosed treatment would be expected to be useful for prevention of disease. One practicing the claimed therapeutic method for prevention of cancer would have no guidance from the specification, and would face an undue experimental burden in developing said method. Thus the long-term prevention of cancer is not supported or enabled by the specification.

The presence or absence of working examples: No working examples are presented demonstrating the success of this therapy for the prevention of cancer in the long term. Those working examples which are provided concern the short-term treatment of an

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existing cancer. It is also noted that the *in vivo* therapy disclosed in section 5.2.11 did not result in complete remission of the cancer being treated over the time period disclosed in figure 4/4 of the drawings.

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art such as gene therapy. See MPEP 2164.

The quantity of experimentation necessary: As mentioned above, the short-term usefulness of a therapy for the treatment of disease is no guarantee of its long-term usefulness for prevention of disease. Because no guidance is given for the use of the claimed therapeutic method for the long-term prevention of disease, one skilled in the art wishing to practice the invention would be unable to do so without first gathering information as to the long-term effectiveness of the therapy.

In particular, one skilled in the art would need to know whether the regular administration of clitocine over a period of decades would adversely affect the health of the subject, given the well-known toxic effects of other translation disrupting compounds such as aminoglycosides, in order to determine the maximum safe dose for chronic use and to devise measures to be taken to reduce any side-effects.

Additionally, one skilled in the art, in order to practice the invention for prevention of cancer, would need to know whether the preventative effect remains potent over the long term. It is possible that long-term administration of clitocine will lead to the emergence of resistant tumors, as is the case for every other cancer drug observed so far.

In order to answer these questions in the absence of any existing data, one skilled in the art, in order to practice the invention, would undertake long-term animal tests, preferably over a period of years, preferably involving a relatively long-lived experimental animal such as dogs or goats rather than the usual rodent models for cancer. The experiments would involve chronic administration of clitocine to a large population of healthy animals, with or without the additional administration of ionizing radiation or chemical carcinogens to put the animals at risk for the development of cancer. Animal experiments include, along with induction of the disease state, administration of the potential pharmaceutical compound and collection and analysis of data, additional burdens associated with compliance with animal welfare regulations, care, feeding, and other maintenance of the animals, dissection of dead animals to collect data, and disposal of dead animals after the protocol is finished. Administering clitocine to a large population of dogs over a period of years, and monitoring the incidence of cancer in said population, is an undue amount of experimentation needed in order to practice the full range of the claimed invention.

Genentech, 108 F.3d at 1366, states that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, especially the breadth of the claims, the unpredictability of the art, and the lack of guidance or working

examples, Applicants fail to provide information sufficient to practice the claimed invention for the prevention of cancer.

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Moss et al. (Reference included with PTO-1449) Moss et al. discloses that Clitocine, the elected chemical species of the instant application, is useful for the inhibition of the growth of various leukemia cell lines *in vitro* according to the experimental protocol disclosed by Ramasamy et al. (reference included with PTO-892) The procedure of Ramasamy et al. comprises adding the compound to be tested to a cell culture of leukemia cells. This procedure therefore involves a method of inhibiting the growth of a cancer cell comprising contacting the cancer cell with an effective amount of a compound having the elected structure. Therefore Moss et al. anticipates the invention of claim 19.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaddurah-Daouk et al. (Reference cited in PTO-892) Kaddurah-Daouk et al. discloses, "a method of inhibiting growth, transformation, and/or metastasis of mammalian cells in which activity of at least one purine metabolic enzyme is elevated." (Column 2, lines 17-20) Kaddurah-Daouk et al. discloses that the class of purine metabolic enzymes includes any enzyme which participates in purine metabolism or affects the ratio of ATP to ADP. Therefore, this class of enzymes includes those enzymes involved in DNA replication, which are elevated in all cancer cells relative to noncancerous cells due to the rapid proliferation of cancer cells. Although one embodiment of this method is directed toward cells transformed by a DNA tumor virus, Kaddurah-Daouk et al. specifically notes that mutations, such as those resulting in the loss of anti-oncogene products Rb, DCC, or p53 may mimic infection by a DNA tumor virus, leading ultimately to elevated activity of a purine metabolic enzyme. (Column 3, lines 33-37) Therefore Kaddurah-Daouk et al. discloses methods of inhibiting the growth of tumors resulting from the nonsense mutation of oncogenes such as Rb, DCC, and p53. A wide variety of drugs may be used in the method of Kaddurah-Daouk et al. For example, clitocine and its derivatives are listed as being useful for this therapeutic method. (column 27, lines 20-21) Kaddurah-Daouk et al. does not disclose as a specific embodiment of this invention a method of treating or preventing cancer resulting from a somatic mutation in DNA or RNA comprising administering an effective amount of clitocine to a patient in need thereof.

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It would have been obvious to one of ordinary skill in the art at the time of the invention to administer an effective amount of clitocine to a subject suffering from a cancer resulting from a somatic mutation in p53 or another oncogene which leads to elevated levels of purine metabolic enzymes. One of ordinary skill in the art would have been motivated to modify the invention of Kaddurah-Daouk et al. in this way in order to treat cancer in a patient suffering therefrom because Kaddurah-Daouk et al. lists clitocine among the various compounds useful for the treatment of cancers with an elevated level of a purine metabolic enzyme, and discloses that a cancerous phenotype with elevated purine metabolic enzymes may be caused by loss-of-function mutations in p53 or other genes. One of ordinary skill in the art would reasonably expected success because the claimed therapeutic method is directed in part to treating cancers for which clitocine is already disclosed to be useful by Kaddurah-Daouk et al.

Thus the invention taken as a whole is *prima facie* obvious.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 11/048659. (unpublished, cited in PTO-892) Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of instant claims 1-19 are completely included within the limitations of claims 1-10 and 18-19 of 11/048659. Claims 1-8 of 11/048659 are drawn to a method of treating or preventing a disease responsive to modulation of premature translation termination and/or nonsense-mediated mRNA decay (including cancers caused by a somatic nonsense mutation as claimed in instant claim 1) comprising administering to a patient in need thereof an effective amount of a compound having the structure (I). (I) is a generic structure which includes the elected compound. Claims 9-10 of 11/048659 are drawn to methods of treating genetic diseases in the same manner. All cancers are genetic diseases.

One of ordinary skill in the art would be motivated to modify the invention in this manner in order to treat cancer in a subject suffering therefrom. One of ordinary skill in the art would reasonably expect success because the invention of instant claims 1-19 is fully included within the scope of claims 1-10 of 11/048659.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Summary

No claims are allowed in this application.

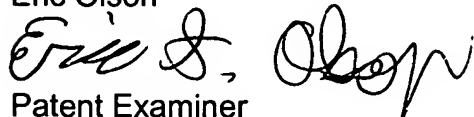
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Eric Olson

Handwritten signature of Eric Olson in black ink.

Patent Examiner

AU 1623

5/25/06

Anna Jiang

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Supervisory Patent Examiner

AU 1623